

### Remarks

This paper is being filed along with a Request for Continued Examination under 37 C.F.R. 1.114.

Claims 12, 14, 15 and 33-37 are pending in the application. Claims 14 and 15 have been amended. New claims 38-40 have been added. Support for amended claim 14 is found, for example, in Example 1 of the specification. Support for new claim 38 is found on pg. 18, para. [0065]. Support for new claims 39 and 40 is found on pg. 13, para. [0050] of the specification and in originally-filed claim 12. No new matter has been added.

In view of the above changes and the following remarks, the Applicants respectfully request reconsideration of the claims.

### Response to the Claim Objections

Claims 12, 14, 15 and 33-37 are objected to for reciting "CB8+T." The term "CB8+T" has been deleted from claim 14, and has been changed to "CD8+T" in claim 15. These changes should obviate the objections to claims 12, 14, 15 and 33-37.

### Response to the section 102(b) rejection

Claims 12, 14, 15 and 33-37 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Grovit-Ferbas et al. The Applicants respectfully traverse the rejection.

To anticipate a claim, a reference must disclose, either expressly or inherently, every feature of the rejected claim. Here, claim 14 has been amended to specify that the HIV used in the claimed composition is *non*-recombinant. Grovit-Ferbas et al. disclose a dendritic cell which contains heat-inactivated HIV<sub>sx</sub>. HIV<sub>sx</sub> is a recombinant virus; see Grovit-Ferbas et al., pg. 5803, 2<sup>nd</sup> col. in the "Results" section, which states "[t]hese studies use the R5-tropic virus HIV<sub>sx</sub>, which contains the HIV<sub>JRFL</sub> envelope in an HIV<sub>NL4-3</sub> backbone."

Dependent claim 12 and new dependent claims 39 and 40 also specify that the inactivated HIV used to prepare the claimed composition is an autologous HIV. Grovit-Ferbas et al. did not use an autologous HIV to prepare their vaccine, but rather used HIV<sub>sx</sub>, which is a recombinant virus.

Claims 36 and 37 are directed to compositions in which the non-recombinant HIV is chemically inactivated, and new claim 38 specifies that the non-recombinant HIV is non-

thermally inactivated. Grovit-Ferbas et al. discloses a dendritic cell which contains heat-inactivated HIVsx. On pg. 3 of the Office Action, the Examiner notes that Grovit-Ferbas et al. discusses chemical inactivation of HIV. However, Grovit-Ferbas et al. discusses chemical inactivation of HIV in an experiment which is different from the experiment in which dendritic cells are exposed to heat-inactivated HIVsx. It is well settled that "an anticipation is not established if in reading a claim on something disclosed in a reference it is necessary to pick, choose and combine various portions of the disclosure not directly related to each other by the teachings of the reference." *Ex parte Beuther*, 71 USPQ2d 1313, 1316 (Bd. Pat. App. & Int. 2003) (citing *In re Arkley*, 172 USPQ 524, 526 (CCPA 1972)).

Thus, Grovit-Ferbas et al. does not disclose every element, either expressly or inherently, of claim 14 or its dependent claims 12, 14, 15 and 33-37, and new dependent claims 38-42. The Applicants therefore request that the 35 U.S.C. § 102(b) rejection be withdrawn.

The Claims are Non-obvious Over Grovit-Ferbas et al.

Claims 12, 14, 15 and 33-37, and new claims 38-40 are also non-obvious over Grovit-Ferbas et al.

To render a claim obvious, a reference must provide one skilled in the art with the suggestion to make the claimed invention, and with a reasonable expectation that the invention can be successfully made. Here, the claims are directed to composition comprising an antigen presenting cell pulsed with an inactivated non-recombinant human immunodeficiency virus (HIV), wherein the composition expands expression of virus-specific CD8+T cells.

Grovit-Ferbas et al. disclose a dendritic cell which contains heat-inactivated *recombinant* HIVsx. This dendritic cell was able to induce a cell-mediated recall response *in vitro*, as measured by the capacity to induce gamma interferon production in the PBMC isolated from three HIV patients, none of whom had a detectable viral load. No data is presented in Grovit-Ferbas et al. which shows that the dendritic cell of Grovit-Ferbas et al. expanded CB8+T cells, or was capable of inducing the CB8+T cells to kill HIV-infected cells. In fact, according to Grovit-Ferbas et al., pg. 5808, 2<sup>nd</sup> column (emphasis added):

Although it is not clear which cell subset produced IFN- $\gamma$  in response to our vaccine preparation, it is likely that the cytokine was secreted by **CD4** cells, since the DC were given an exogenous (antigen) for processing.

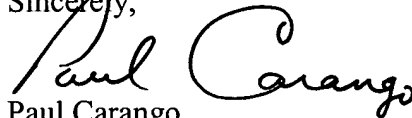
The compositions of claims 12, 14-15 and 33-37 and new claims 38-40 expand expression of virus-specific CD8+T cells. At best, the dendritic cells of Grovit-Ferbas et al., which contain *recombinant* HIV, elicit IFN- $\gamma$  production from CD4 cells. There is no evidence that the Grovit-Ferbas et al. dendritic cells can expand CB8+T cells. Indeed, Grovit-Ferbas et al. teaches that dendritic cells containing recombinant HIVsx elicit a CD4 cell response. Also, there is no suggestion in Grovit-Ferbas et al. to load dendritic cells with other HIV strains in order to achieve a different response.

Grovit-Ferbas et al. therefore does not suggest to one skilled in the art to prepare a composition comprising an antigen presenting cell pulsed with an inactivated non-recombinant human immunodeficiency virus (HIV), wherein the composition expands expression of virus-specific CD8+T cells, or that such a composition could be successfully made. Thus, Grovit-Ferbas et al. does not render claims 12, 14-15 and 33-37 and new claims 38-40 obvious.

Conclusion

In view of the foregoing, the Applicants respectfully submit the Application is now in condition for allowance, which is respectfully requested.

Sincerely,

A handwritten signature in black ink that reads "Paul Carango". The signature is fluid and cursive, with the first name "Paul" and last name "Carango" clearly distinguishable.

Paul Carango

Reg. No. 42,386

Attorney for Applicants

PC:rb  
215.656.3320